General

Guideline Title

Self-expandable metal stents for obstructing colonic and extracolonic cancer: European Society of Gastrointestinal Endoscopy (ESGE) clinical guideline.

Bibliographic Source(s)

van Hooft JE, van Halsema EE, Vanbiervliet G, Beets-Tan RGH, DeWitt JM, Donnellan F, Dumonceau J-M, Glynne-Jones RGT, Hassan C, JimÃ©nez-Perez J, Meisner S, Muthusamy VR, Parker MC, Regimbeau J-M, Sabbagh C, Sagar J, Tanis PJ, Vandervoort J, Webster GJ, Manes G, Barthet MA, Repici A, European Society of Gastrointestinal Endoscopy. Self-expandable metal stents for obstructing colonic and extracolonic cancer: European Society of Gastrointestinal Endoscopy (ESGE) clinical guideline. Endoscopy. 2014 Nov;46(11):990-1002. [128 references] PubMed

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Recommendations

Major Recommendations

Definitions for levels of evidence (high, moderate, low, very low) and strength of recommendation (strong, weak) are provided at the end of the "Major Recommendations" field.

General Considerations Before Stent Placement

Prophylactic colonic stent placement is not recommended. Colonic stenting should be reserved for patients with clinical symptoms and imaging evidence of malignant large-bowel obstruction, without signs of perforation (strong recommendation, low quality evidence).

A contrast-enhanced computed tomography (CT) scan is recommended as the primary diagnostic tool when malignant colonic obstruction is suspected (strong recommendation, low quality evidence).

Examination of the remaining colon with colonoscopy or CT colonography (CTC) is recommended in patients with potentially curable obstructing colonic cancer, preferably within 3 months after alleviation of the obstruction (strong recommendation, low quality evidence).

Colonic stenting should be avoided for diverticular strictures or when diverticular disease is suspected during endoscopy and/or CT scan (strong recommendation, low quality evidence). Pathological confirmation of malignancy by endoscopic biopsy and/or brush cytology is not necessary in an urgent setting, such as before stent placement. However, pathology results may help to modify further management of the stented patient (strong recommendation, low quality evidence).

Preparation of obstructed patients with an enema to clean the colon distal to the stenosis is suggested to facilitate the stent placement procedure (weak recommendation, low quality evidence). Antibiotic prophylaxis in obstructed patients undergoing colon stenting is not indicated because the risk of post-procedural infections is very low (strong recommendation, moderate quality evidence).

Colonic stent placement should be performed or directly supervised by an experienced operator who has performed at least 20 colonic stent placement procedures (strong recommendation, low quality evidence).

Technical Considerations of Stent Placement

Colonic stent placement is recommended with the combined use of endoscopy and fluoroscopy (weak recommendation, low quality evidence).

Stricture dilation either before or after stent placement is discouraged in the setting of obstructing colorectal cancer (strong recommendation, low quality evidence).

Covered and uncovered self-expandable metal stents (SEMS) are equally effective and safe (high quality evidence). The stent should have a body diameter ≥24 mm (strong recommendation, low quality evidence) and a length suitable to extend at least 2 cm on each side of the lesion after stent deployment (weak recommendation, low quality evidence).

Surgical resection is suggested as the preferred treatment for malignant obstruction of the proximal colon in patients with potentially curable disease (weak recommendation, low quality evidence). In a palliative setting, SEMS can be an alternative to emergency surgery (weak recommendation, low quality evidence).

SEMS placement is a valid alternative to surgery for the palliation of malignant extracolonic obstruction (weak recommendation, low quality evidence). The technical and clinical success rates of stenting for extracolonic malignancies are inferior to those reported in stenting of primary colonic cancer (low quality evidence).

There is insufficient evidence to discourage colonic stenting based on the length of the stenosis (weak recommendation, low quality evidence) or the degree of obstruction (strong recommendation, low quality evidence).

Clinical Indication: SEMS Placement as a Bridge to Elective Surgery

Colonic SEMS placement as a bridge to elective surgery is not recommended as a standard treatment of symptomatic left-sided malignant colonic obstruction (strong recommendation, high quality evidence). For patients with potentially curable left-sided obstructing colonic cancer, stent placement may be considered as an alternative to emergency surgery in those who have an increased risk of postoperative mortality, i.e., American Society of Anesthesiologists (ASA) ≥III and/or age >70 years (weak recommendation, low quality evidence).

A time interval to operation of 5 to 10 days is suggested when SEMS is used as a bridge to elective surgery in patients with potentially curable left-sided colon cancer (weak recommendation, low quality evidence).

Clinical Indication: Palliative SEMS Placement

SEMS placement is the preferred treatment for palliation of malignant colonic obstruction (strong recommendation, high quality evidence).

Patients who have undergone palliative stenting can be safely treated with chemotherapy without antiangiogenic agents (strong recommendation, low quality evidence). Given the high risk of colonic perforation, it is not recommended to use SEMS as palliative decompression if a patient is being treated or considered for treatment with antiangiogenic therapy (e.g., bevacizumab) (strong recommendation, low quality evidence).

Adverse Events Related to Colonic Stenting

When stent obstruction or migration occurs in the palliative setting, endoscopic re-intervention by stent-in-stent placement or SEMS replacement is suggested (weak recommendation, low quality evidence). Surgery should always be considered in patients with stent-related perforation (strong recommendation, low quality evidence).

Definitions

Levels of Evidence According to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) System

Evidence Level	
High quality	One or more well-designed and well-executed randomized controlled trials (RCTs) that yield consistent and directly applicable results.

	This level also means that further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality	RCTs with important limitations (i.e., biased assessment of the treatment effect, large loss to follow-up, lack of blinding, unexplained heterogeneity), indirect evidence originating from similar (but not identical) populations of interest, and RCTs with a very small number of participants or observed events. In addition, evidence from well-designed controlled trials without randomization, from well-designed cohort or case–control analytic studies, and from multiple time series with or without intervention is in this category. This level also means that further research will probably have an important impact on confidence in the estimate of effect and may change the estimate.
Low quality	Observational studies would typically be rated as low quality because of the risk for bias.[1] This level also means that further research is very likely to have an important impact on confidence in the estimate of effect and will probably change the estimate.
Very low quality[2]	Evidence is conflicting, of poor quality, or lacking, and hence the balance of benefits and harms cannot be determined. Any estimate of effect is very uncertain as evidence is either unavailable or does not permit a conclusion.

[1]Quality of evidence based on observational studies may be rated as moderate or even high, depending on circumstances under which evidence is obtained from observational studies. Factors that may contribute to upgrading the quality of evidence include a large magnitude of the observed effect, a dose–response association, or the presence of an observed effect when all plausible confounders would decrease the observed effect.

[2]Insufficient evidence to determine for or against routinely providing a service.

Strength of Recommendations According to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) System

Strength of Recommendation	
Strong	Benefits clearly outweigh risks and burden, or vice versa. Usually stated as "is recommended."
Weak	Benefits closely balanced with risks and burden. Usually stated as "is suggested."

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Obstructing colonic and extracolonic cancer

Note: Unless indicated otherwise the recommendations in this Guideline only apply to left-sided colon cancer arising from the rectosigmoid colon, sigmoid colon, descending colon, and splenic flexure, while excluding rectal cancers and those proximal to the splenic flexure, and other causes of colonic obstruction including extracolonic obstruction.

Guideline Category

Management

Treatment

Clinical Specialty

Colon and Rectal Surgery

Gastroenterology

Oncology

Radiology

Intended Users

Physicians

Guideline Objective(s)

To provide practical guidance regarding the use of self-expandable metal stents (SEMS) in the treatment of malignant colonic obstruction

Target Population

Patients with obstructing colonic and extracolonic cancer

Interventions and Practices Considered

1. Contrast-enhanced computed tomography (CT) scan
2. Colonoscopy or CT colonography (CTC) scan after alleviation of obstruction
3. Pathological confirmation of malignancy
4. Patient preparation (enema)
5. Performance or supervision of colonic stent placement by an experienced operator
6. Placement with combined use of endoscopy and fluoroscopy
7. Considerations for type of self-expandable metal stent (SEMS): covered or uncovered, size
8. Surgical resection for malignant obstruction
9. Stenting as a bridge to elective surgery (indications and considerations)
10. Palliative stenting including considerations for stenting in conjunction with chemotherapy
11. Management of stent-related adverse events (stent obstruction or migration, stent-related perforation)

Note: The following were considered but not recommended: prophylactic colon stent placement, colonic stenting for diverticular strictures or when diverticular disease is suspected during endoscopy and/or CT scan, antibiotic prophylaxis before stent placement, stricture dilation either before or after stent placement, palliative stenting in patients being treated or considered for treatment with antiangiogenic therapy.

Major Outcomes Considered

- Technical success rates and complications of self-expandable metal stent (SEMS) placement
- Safety/effectiveness
- Morbidity and mortality
- Survival
- Length of hospital stay
- Oncological outcome (local recurrence rate, metastatic disease)
- Adverse events (migration, occlusion, malfunction, perforation)

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Each task force performed a systematic literature search to prepare evidence-based and well-balanced statements on their assigned key questions. The coordinating team independently performed systematic literature searches with the assistance of a librarian. The Medline, EMBASE and Trip databases were searched for studies published after January 1, 2000 for most key questions and included at minimum the following key words: colon, cancer, malignancy or neoplasm, obstruction and stents. The searches for question 3A (clinical indications: self-expandable metal stents [SEMS] placement as a bridge to elective surgery) and 3B (clinical indication: palliative SEMS placement) included articles published after January 1, 2007. All articles studying the use of SEMS for malignant large-bowel obstruction were selected by title or abstract. The literature searches were updated until January 2014.

Number of Source Documents

The European Society of Gastrointestinal Endoscopy (ESGE) provided literature search results to the National Guideline Clearinghouse (NGC) as internal companion documents.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Levels of Evidence According to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) System

Evidence Level	
High quality	One or more well-designed and well-executed randomized controlled trials (RCTs) that yield consistent and directly applicable results. This level also means that further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality	RCTs with important limitations (i.e., biased assessment of the treatment effect, large loss to follow-up, lack of blinding, unexplained heterogeneity), indirect evidence originating from similar (but not identical) populations of interest, and RCTs with a very small number of participants or observed events. In addition, evidence from well-designed controlled trials without randomization, from well-designed cohort or case–control analytic studies, and from multiple time series with or without intervention is in this category. This level also means that further research will probably have an important impact on confidence in the estimate of effect and may change the estimate.
Low quality	Observational studies would typically be rated as low quality because of the risk for bias.[1] This level also means that further research is very likely to have an important impact on confidence in the estimate of effect and will probably change the estimate.
Very low quality[2]	Evidence is conflicting, of poor quality, or lacking, and hence the balance of benefits and harms cannot be determined. Any estimate of effect is very uncertain as evidence is either unavailable or does not permit a conclusion.

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[2]Insufficient evidence to determine for or against routinely providing a service.

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

All articles studying the use of self-expandable metal stents (SEMS) for malignant large-bowel obstruction were selected by title or abstract. After further exploration of the content, the article was then included and summarized in the literature tables of the key topics when it contained relevant data (see online Appendix e2, Tables e1–e5 [see the "Availability of Companion Documents" field"]). All selected articles were graded by the level of evidence and strength of recommendation according to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system (see the "Rating Scheme for the Strength of the Evidence" and "Rating Scheme for the Strength of the Recommendations" fields).

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

The European Society of Gastrointestinal Endoscopy (ESGE) commissioned this Guideline and appointed a guideline leader who invited the listed authors to participate in the project development. The key questions were prepared by the coordinating team and then approved by the other members. The coordinating team formed task force subgroups, each with its own leader, and divided the key topics among these task forces (see online Appendix e1 [see the "Availability of Companion Documents" field]).

Each task force proposed statements on their assigned key questions which were discussed and voted on during the plenary meeting held in February 2014, Düsseldorf, Germany. In March 2014, a draft prepared by the coordinating team was sent to all group members.

Rating Scheme for the Strength of the Recommendations

Strength of Recommendations According to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) System

Strength of Recommendation	
Strong	Benefits clearly outweigh risks and burden, or vice versa. Usually stated as "is recommended."
Weak	Benefits closely balanced with risks and burden. Usually stated as "is suggested."

Cost Analysis

No clear conclusions may be drawn about differences in costs between self-expandable metal stents (SEMS) as bridge to surgery and emergency surgery procedures. In the two randomized controlled trials (RCTs) that compared costs between SEMS as bridge to surgery and emergency surgery, stenting seems to be the more costly strategy. Cost-effectiveness depends on the rate of stent complications, in particular perforation, and a greater benefit of stenting is expected in high risk surgical patients.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

After agreement on a final version, the manuscript was submitted to *Endoscopy* for publication. The journal subjected the manuscript to peer

review and the manuscript was amended to take into account the reviewers' comments. All authors agreed on the final revised manuscript. The final revised manuscript was then reviewed and approved by the Governing Board of the American Society for Gastrointestinal Endoscopy (ASGE).

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

- Appropriate use of self-expandable metal stents (SEMS) for obstructing colonic and extracolonic cancer
- Two noncomparative studies addressed the learning curve of a single endoscopist performing colonic stent placement. Both showed an increase in technical success and a decrease in the number of stents used per procedure after performance of at least 20 procedures. Two other retrospective series have shown that operator experience affects stenting outcome. The first reported significantly higher technical and clinical success rates when the stent was inserted by an operator who had performed at least 10 SEMS procedures. The second showed a significantly increased immediate perforation rate when colonic stent placement was performed by endoscopists inexperienced in pancreaticobiliary endoscopy. The authors of the latter article explained the lower immediate perforation rate by the skills that therapeutic endoscopic retrograde cholangiopancreatography (ERCP) endoscopists have in traversing complex strictures, understanding fluoroscopy, and deploying stents.

Potential Harms

Colonic self-expandable metal stents (SEMS) placement in patients with malignant large-bowel obstruction is associated with potential adverse events. However, the 30-day stent-related mortality rate is less than 4%.

Adverse events related to colonic stent placement are usually divided into early (≤30 days) and late (>30 days). The main early complications are perforation (range 0%–12.8%), stent failure after technically successful stent deployment (range 0%–11.7%), stent migration (range 0%–4.9%), re-obstruction (range 0%–4.9%), pain (range 0%–7.4%), and bleeding (range 0%–3.7%). Late adverse events related to SEMS mainly include re-obstruction (range 4.0%–22.9%) and stent migration (range 1.0%–12.5%), and more rarely perforation (range 0%–4.0%), although one randomized controlled trial (RCT) reported late perforations in 4 out of 10 stent patients. Other SEMS complications reported less frequently in the literature are tenesmus (up to 22%, related to rectal SEMS), incontinence, and fistula.

Stent-related perforation may result from different causes which can be classified as: (i) guidewire or catheter malpositioning; (ii) dilation of the stricture before or after stent placement; (iii) stent-induced perforation (tumor and nontumor local perforation); and (iv) proximal colonic distension because of inadequate colonic decompression or excessive air insufflation. The final outcome of stent perforation has been inconsistently reported in the literature, although a perforation-related mortality rate of 50% is observed in a number of prospective and retrospective studies. Furthermore, there are strong indications that perforation compromises the oncological outcome in patients with colorectal cancer. Concurrent bevacizumab therapy, intraprocedural and post-stenting stricture dilation, and diverticular strictures were identified by several studies as risk factors for stent-related perforation.

Stent migration can occur at any time following colonic stenting. Factors that have been identified to correlate with the occurrence of migration are use of covered SEMS and of small-diameter (<24 mm) stents, and there is some evidence that chemotherapy may also be associated with stent migration by the mechanism of tumor shrinkage.

Tumor ingrowth/overgrowth is the main cause of stent re-obstruction and usually occurs during the long-term course of stent therapy. The use of uncovered SEMS is a risk factor for tumor ingrowth. One retrospective series focusing on predictive factors of stent occlusion found that <70% stent expansion within the first 48 hours is also predictive for the occurrence of re-obstruction.

Contraindications

Contraindications

- The only absolute contraindication for colonic stenting is perforation.
- Symptomatic bowel obstruction is a relative contraindication to oral bowel cleansing.

Qualifying Statements

Qualifying Statements

European Society of Gastrointestinal Endoscopy (ESGE) guidelines represent a consensus of best practice based on the available evidence at the time of preparation. They may not apply in all situations and should be interpreted in the light of specific clinical situations and resource availability. Further controlled clinical studies may be needed to clarify aspects of these statements, and revision may be necessary as new data appear. Clinical consideration may justify a course of action at variance to these recommendations. ESGE guidelines are intended to be an educational device to provide information that may assist endoscopists in providing care to patients. They are not rules and should not be construed as establishing a legal standard of care or as encouraging, advocating, requiring, or discouraging any particular treatment.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

IOM Domain

Effectiveness

Safety

Identifying Information and Availability

Bibliographic Source(s)

van Hooft JE, van Halsema EE, Vanbiervliet G, Beets-Tan RGH, DeWitt JM, Donnellan F, Dumonceau J-M, Glynne-Jones RGT, Hassan C, JimÃ©nez-Perez J, Meisner S, Muthusamy VR, Parker MC, Regimbeau J-M, Sabbagh C, Sagar J, Tanis PJ, Vandervoort J, Webster GJ,

Manes G, Barthet MA, Repici A, European Society of Gastrointestinal Endoscopy. Self-expandable metal stents for obstructing colonic and extracolonic cancer: European Society of Gastrointestinal Endoscopy (ESGE) clinical guideline. Endoscopy. 2014 Nov;46(11):990-1002. [128 references] PubMed

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2014 Nov

Guideline Developer(s)

European Society of Gastrointestinal Endoscopy - Medical Specialty Society

Source(s) of Funding

European Society of Gastrointestinal Endoscopy

Guideline Committee

ESGE Guideline Committee

Composition of Group That Authored the Guideline

Authors: Jeanin E. van Hooft, Department of Gastroenterology and Hepatology, Academic Medical Center, Amsterdam, The Netherlands; Emo E. van Halsema, Department of Gastroenterology and Hepatology, Academic Medical Center, Amsterdam, The Netherlands; Geoffroy Vanbiervliet, Centre Hospitalier Universitaire de l'Archet, Pôle digestif, Nice, France; Regina G. H. Beets-Tan, Department of Radiology, Maastricht University Medical Center, The Netherlands; John M. DeWitt, Department of Gastroenterology and Hepatology, Indiana University Medical Center, Indianapolis, Indiana, United States; Fergal Donnellan, UBC Division of Gastroenterology, Vancouver General Hospital, Vancouver, Canada; Jean-Marc Dumonceau, Gedyt Endoscopy Center, Buenos Aires, Argentina; Robert G. T. Glynne-Jones, Mount Vernon Cancer Centre, Northwood, Middlesex, UK; Cesare Hassan, Digestive Endoscopy Unit, Catholic University, Rome, Italy; Javier Jiménez-Perez, Endoscopy Unit, Gastroenterology Department, Complejo Hospitalario de Navarra, Pamplona, Spain; Søren Meisner, Endoscopy Unit, Digestive Disease Center, Bispebjerg University Hospital, Copenhagen, Denmark; V. Raman Muthusamy, Division of Gastroenterology and Hepatology, David Geffen School of Medicine at University of California Los Angeles, Los Angeles, California, United States; Michael C. Parker, Royal College of Surgeons of England, London, UK; Jean-Marc Regimbeau, Department of Digestive and Oncological Surgery, University Hospital of Amiens, France; Charles Sabbagh, Department of Digestive and Oncological Surgery, University Hospital of Amiens, France; Jayesh Sagar, Department of Colorectal Surgery, Royal Surrey County Hospital, Guildford, UK; Pieter J. Tanis, Department of Surgery, Academic Medical Center, Amsterdam, The Netherlands; Jo Vandervoort, Department of Gastroenterology, Onze-Lieve-Vrouwziekenhuis, Aalst, Belgium; George J. Webster, Department of Gastroenterology, University College Hospital, London, UK; Gianpiero Manes, Department of Gastroenterology and Endoscopy, Guido Salvini Hospital, Garbagnate Milanese/Rho, Milan, Italy; Marc A. Barthet, Department of Gastroenterology, Hôpital Nord, Aix Marseille Université, Marseille, France; Alessandro Repici, Digestive Endoscopy Unit, Istituto Clinico Humanitas, Milan, Italy

Financial Disclosures/Conflicts of Interest

Competing Interests

J. E. van Hooft: consultancy work for Cook Medical, Boston Scientific, Abbott and Covidien. J. M. Dewitt: consultant for Boston Scientific, Olympus America, and Apollo Endosurgery without grant nor honoria. S. Meisner: consultancy work for Coloplast Denmark, Olympus Denmark, Olympus Europa, Boston Scientific. Dr. V. Muthusami: consultant for Boston Scientific. Dr. A. Repici received a consulting fee and speech fee

from Boston Scientific and research grants from Fujifilm, Covidien GI solution and Merit Medical. G. Webster: Advisory Board for Cook Medical and Boston Scientific. All other authors disclosed no financial relationships relevant to this publication.

Guideline Endorser(s)

American Society for Gastrointestinal Endoscopy - Medical Specialty Society

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Available from the European Society of Gastrointestinal Endoscopy (ESGE) Web site .

Availability of Companion Documents

The following are available:

- Dumonceau J-M, Hassan C, Riphaus A, Ponchon T. European Society of Gastrointestinal Endoscopy (ESGE) guideline development policy. Endoscopy 2012;44: 626-9. Available from the European Society of Gastrointestinal Endoscopy (ESGE) Web site .
- van Hooft JE, van Halsema EE, Vanbiervliet G, Beets-Tan RGH, DeWitt JM, Donnellan F, Dumonceau J-M, Glynne-Jones RGT, Hassan C, Jiménez-Perez J, Meisner S, Muthusamy VR, Parker MC, Regimbeau J-M, Sabbagh C, Sagar J, Tanis PJ, Vandervoort J, Webster GJ, Manes G, Barthet MA, Repici A. European Society of Gastrointestinal Endoscopy. Self-expandable metal stents for obstructing colonic and extracolonic cancer: European Society of Gastrointestinal Endoscopy (ESGE) clinical guideline. Online appendices. Endoscopy. 2014 Nov;46(11). 51 pages. Available from the Endoscopy Web site .

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on December 14, 2016. The information was verified by the guideline developer on January 2, 2017.

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